REMARKS

Applicant thanks the Examiner for granting an interview on October 12, 2005.

The foregoing amendments in claims 1 and 7 respond to the Final Office Action mailed on August 23, 2005 and follow up on certain suggestions made by the Examiner at the interview to state the subject matter of the present invention more clearly. As discussed at the interview, the subject matter of claim 2 specifying that the "information" of original claim 1 is an "image or effect" has been added to claim 1, and to claim 7 to specify that the relief produces "images and effects." These amendments also make it clear that these images and effects are seen by the "unaided eye". They are directly visible by a person and not, for example, like information on a CD that can only be read by a machine. Support for this amendment is found specifically on page 5, lines 5 and 8, and page 11, lines 10-11, and throughout the specification through references to "visible," "visible indicator," "visual indication," and "visible light."

Claim 2 is then amended to reflect changed antecedents in claim 1.

Both claims 1 and 7 have also been amended to specify that the "material" of claim 1 and "layer" of claim 7 are an edible material, as well as one that is thermoformable and stable. Support for this amendment is also replete throughout the specification, but specifically at, page 1, lines 19 and 21-24, page 4, line 13, page 5, line 10, page 11, line 22, and page 14, line 7..

Both claims 1 and 7 are also amended to define the structure that produces the images and effects as a "diffraction relief" to emphasize that the structure works by diffracting light. This diffraction relief is further defined as a pattern of ridges and grooves that interact with visible light to produce the images and effects that can be seen with the unaided eye. This defines the dimensions and structure as one of a scale to interact with light waves, i.e., microscopic.

Such a relief and its interaction with light waves was discussed during the interview. The effects and images produced by it were demonstrated by photographs of pharmaceuticals embodying the invention that display various colors and images (attached hereto as Exhibits 1-3). Extremely highly magnified images of diffraction reliefs according to the present invention (attached hereto as Exhibits 4-5), were also shown to the Examiner.

As explained at the interview, the pattern of ridges and grooves are of a size that interacts with light to cause light waves to interfere with one another, that is, the light waves combine (increase in amplitude as a peak of one wave meets a peak of another wave) or cancel one another (decease in amplitude as a peak of one wave meets a trough of another wave) at different points in space, depending on the phase relationship between the waves. This is the nature of a diffraction relief.

The scale of "micro" in "microrelief" in original claims 1 and 7 is now expressly related to the diffraction of visible light using a diffraction relief.

Claims 6 and 8 are now cancelled in view of these amendments in claims 1 and 7. The dependencies of claims 9 and 10 are accordingly changed from 8 to 7, and claim 14 is now dependent solely on claim 9, not 8 and 9.

In claim 15, "or chemical" bond is deleted to emphasize the heat fusion of the material as the adherent. Heat fusion bonding in this context is believed to be novel per se. In claim 16, "vegetable gum" is deleted as it is a chemical bond adherent.

In claims 19, 21, 22 and 23, "microrelief" is changed to "diffraction relief" to be consistent with the amended claims from which they depend, directly or indirectly.

Also in claim 19, the phrase "over time" is added to make it clear that this change in appearance is one that occurs over time to reflect the history of the dosage form, and in particular its environmental history. Support for this phrase appears at least at page 19, line 4.

Additional support for amendments not involving language previously in a claim in the exact same form is cited in the following section.

I. Claimed Features of the Present Invention Not Found In or Suggested By the Reif '200 Reference

The present invention relates to "pharmaceutical dosage forms and other edible products bearing a microrelief, and in particular a high resolution diffraction relief." (Specification, page 4, lines 30-31.) Independent claim 1 as amended specifies that the dosage form includes a layer of material "bearing a diffraction relief." Independent claim 7, as amended, specifies "a diffraction relief in said layer." While "microrelief," "diffraction relief," and "diffraction grating" are used substantially interchangeably in the specification, "microrelief" in claims 1 and 7 has been amended to "diffraction relief" to make it clear that the regular pattern of the relief interacts with light, and to do so it is sized on a scale of a wavelength of the incident light. "Diffraction" therefore defines the size and spatial frequency of the structure producing the diffraction on a scale of the dimension of the light wave, that is, "micro," as that term is used and defined in this application.

The specification defines "microrelief," at page 9, line 33 to page 10, line 1, to mean:

> "a regular pattern of grooves and ridges or the like that displays optical information or a visual effect, when exposed to suitable radiant energy."

At the top of page 10, "microrelief" as well as "diffraction grating" and "grating" is specified to include:

> (1) patterns of the grooves and ridges produced through laser light interference, with ruling engines, and with other known techniques which can be subsequently transferred to the dosage form by a mold or radiant energy and (2) visual information, images and effects produced by these patterns of grooves and ridges when properly illuminated.

Further, on page 10, lines 14-15, the "dimension of the diffraction relief are proportional to the wavelength of the light it is to interact with."

As will be discussed in greater detail below, the sole reference relied on to reject the pending claims has no such diffraction relief.

An aspect of this invention is the physical structure of the diffraction relief interacting with visible light incident on it produces colors and images, not any ink printed on the dosage forms.

Claim 1 further specifies that the claimed material, and the diffraction relief in the material, are "stable." As stated in the specification, page 3, lines 13-16:

> The microrelief should have a long shelf life, which requires a high resistance to changes in shape on the micron scale due to applied mechanical stresses, and degradation due to temperature changes or to the absorption of moisture. Such a microrelief is termed "stable". (Emphasis supplied.)

Along the same line, on page 11, the material of the outer layer 12 is described as being one that:

> "can receive a high resolution diffraction relief 16, and retain that relief pattern reliably for the intended life of the product, under anticipated conditions of manufacture, handling, storage and use."

Further, at page 11, line 26-27, the specification makes it clear that the material retains a "grating with a phase displacement on the scale of the wave length of light ..." On at least page 10, lines 13-15, and page 19, lines 20-23, it is clear that micro and "scale of the wavelength of light" refers to ridge and groove structure or the like with a ridge to adjacent groove spacing on the order of ½ to 1 micron (1/1,000,000 of a meter). And as noted above, it is also express that to be stable, the diffraction relief is highly resistant to changes in these minute dimensions.

As will be discussed in greater detail below, the sole reference relied on to reject the pending claims has no teaching or suggestion of such stability.

Applicant's claimed layer and a diffraction relief in the layer are expressly characterized in independent claims 1 and 7 as "thermoformable". Thermoforming is described in the specification as characteristic of the claimed material in connection with the ability to receive the diffraction relief by thermoforming. Thermoforming in the context of the present invention is summarized, e.g., on page 11, in the second full paragraph. It specifies there that the material layer is initially solid, is capable of being softened by heat, when softened, is capable of having a very fine ("micro") pattern pressed into it using an embossing member, is capable of cooling rapidly with this pattern impressed, and then retains the pattern through the mechanical stress of a de-molding as the pattern embossing element is withdrawn from the layer.

As will be discussed in greater detail below, the sole reference relied on to reject the pending claims has no such teaching or suggestion of a thermoformable layer carrying a diffraction relief, or one where the diffraction relief is stable.

II. The Disclosure of the Reif '200 Reference

Applicant respectfully traverses the rejection of all pending claims 1-28 under 35 USC 102(b) as fully anticipated by U.S. Patent No. 4,036,200 to Reif.

The Reif '200 patent has no disclosure of a diffraction relief as described and claimed in the present application.

The Examiner argues that a reference in the Reif patent to "printing" on a dosage form teaches this claimed limitation. It does not. Reif '200 teaches conventional printing. At Col. 33, lines 6-9, it delineates printing as "offset and direct letterpress; offset gravure; lithography; electrostatic powder gravure; electrostatic screen stencil; ink jet and the like". This "printing" is clearly not the creation of a pattern of minute ridges and grooves with dimensions on the order of a wavelength of light whose interaction radiant energy such as with visible light creates an image or effect. There is no mention in Reif '200 of "diffraction relief," "microrelief," "relief," "diffraction grating," "grating," or any like "regular pattern of grooves and ridges." Nor is there a suggestion of same. Nor is there any mention or suggestion of the Reif '200 dosage unit being able to create visual images or effects through the interaction of radiant energy such as visible light with a pattern of grooves and ridges, or the like.

The present application uses the words "print" and "printing," but not in the usual sense of these words. They are used to describe a way to apply a layer of the material to a core of a dosage form. This layer, thus applied, does not create an image or effect or convey "information." Rather, this is done by the diffraction relief which is created in the material after this "printing-like" application of the material to a core. Indeed, a stated object of the present invention is to create colors, symbols and effects using inks or dyes required by conventional printing. Reif '200 therefore teaches away from the present invention, back to prior art ink printing.

Nor is there any teaching or suggestion that any "web" taught by Reif '200 can or should be thermoformed to receive a diffraction relief pattern of grooves and ridges. In the Reif patent section on "Finishing and Printing," Cols. 32-33, discusses creation of "uniformity" and "complete continuity" in the outer surface and a finish "gloss." (Col. 32, lines 31-39). Reif teaches a smooth, glossy outer surface that may receive and carry conventional printing. This teaches directly away from a surface of grooves and ridges, or the use of a pattern of microscopic grooves and ridges to carry information.

Reif not only does not teach the claimed invention, in all material aspects it teaches away. The overall thrust of the Reif '200 patent is to produce a delivery system for an active ingredient that is released quickly and in a controlled manner when used. (See, e.g. Reif Fig. 7) It is a control release delivery system; it is not directed to creating visual effects and images.

Turning to specific features, Reif '200 teaches a web that supports active ingredients. This web can use materials also used to form Applicant's "layer" (claim 1) and "outer layer" or coating (claim 7). However, Reif '200 teaches that its web materials are "formulated to self destruct in contact with water or gastric fluid." (Col. 6, lines 64-66). The web material can 1) "swell upon contact with water thereby disrupting or breaking the web," or 2) have its soluble constituents go into solution and the insoluble constituents precipitate "causing the web to rupture." (Col. 7, lines 3-7). In a section of the Reif patent entitled "Dissolution," it goes further to say that the "novel dosage forms of the subject invention dissolve much more rapidly than in conventional capsules tested." (Col. 35, lines 29-31). Clearly, materials touted for their unusual ability to swell and dissolve are not ones that one would expect to be stable "on the micron level" through exposure to humid air.

Reif '200 also teaches away from the present invention stressing that it is important to avoid any "coating" applied to the "finished dosage form." Reif

states at Col. 4, lines 63-66, "...the medicament contained therein is completed internalized within the dosage forms yet, in most instances, there is no coating per se applied to the finished dosage form." The present invention requires that the layer of material that carries a diffraction relief be on the outside of the dosage form, as the diffraction relief must interface with air to interact with light. Claim 7 specifies that the layer is an "outer layer overlying" a core that includes an active ingredient and a carrier. Dependent claim 2 specifies that the layer is an "all-covering" or "partially covering" coating with respect to a core.

The Reif patent also stresses the importance of its "core" being only an active ingredient. As stated at the outset of the Detailed Description of the Invention, Col. 3, lines 36-42:

> First, the fact that the dosage units of the present invention are substantially free of conventional pharmaceutical adjunct material results in savings in cost of raw materials and manufacturing procedures as well as eliminating potential incompatibilities caused by the presence of such materials.

This advantage appears even in the Brief Statement of the Invention, Col. 3, lines 17-19.

In sharp contrast, applicant's claim 7, and the claims dependent from it, all specify that the core includes an active ingredient and a carrier.

Reif '200 also does not teach or suggest important features expressly defined by applicant's dependent claims.

Claim 2, and claims 3-5 dependent from claim 2, specify that the "images and effects conveyed by the claimed microrelief are holographic. Reif '200 is devoid of any teaching or the slightest suggestion of a dosage form that creates holographic images or effects. The same is true regarding the diffraction grating specified in claims 6 and 8 and claims 9, 10, and 19-24 dependent,

directly or indirectly, from claim 8. A diffraction grating by definition interacts with light.

Tailoring a dosage form having an outer layer of the specified material and including a diffraction relief to give a visual indication of the environmental history of the dosage form by changing its appearance is not found in Reif '200 or in any way suggested by the disclosure of Reif '200. Claims 19-24 are not found in or suggested by Reif '200. They are highly novel and patentable.

Still further, Reif '200 has no teaching of a dosage form structure that resists twinning during a pan coating of the claimed layer onto a core, as defined by claims 25-28. Twinning is uniquely problematic in producing commercially practical holographic tablet forms. See, e.g., the specification at page 20, lines 17-18. The dosage form surface, in this invention (but not in the case of printing), also acts like a lens or optical element. To produce an acceptable hologram, the surface should be flat (or made up of flat segments). However, that directly conflicts with the coating process by causing more twinning (thereby rendering the tablets unusable for any application). The present invention describes and claims a unique solution that allows both the maximum optical functionality of the hologram on the surface of the tablet, and at the same time minimizes the problem of twinning that would otherwise happen during coating flat-sectioned, holographically-friendly tablets.

Not only does Reif '200 not recognize this twinning/lens problem, it expressly teaches away from an outer coating. Reif teaches that to obtain a quick release medicament delivery system one deposits an active ingredient on a web, folds or otherwise fabricates the web supporting the active ingredient, and then finishes the fabricated web by removing flashing and/or printing on the dosage form. There is no pan coating in Reif '200; twinning is not an issue. Reif '200 teaches nothing about controlling twinning, let alone controlling twinning when optical considerations militate for contrary constructions.

Applicants have supplied herewith as Exhibit 6 a color photograph of a dosage form, a form of commercial pill, but here one manufactured according to the present invention to include the claimed outer layer carrying a microrelief. The resulting holographic effect produced by the microrelief is a rainbow-like array of colors over two faces of the pill around the usual visual product identifiers for this product. Reif '200 does not teach a product that has a diffraction relief, nor one capable of producing this effect.

The present claims define clear and strong differences over the Reif '200 patent. Reif does not teach or suggest a dosage form with a diffraction relief, or an outer layer of a material that is thermoformable to receive the diffraction relief, or stable to retain it. Nor does Reif '200 teach or suggest, inter alia, a dosage form with a diffraction relief constructed to provide a visual indication of the environmental history of the product as a change in its appearance, or with a construction that resists twinning, or which can produce images or effects that are seen with the unaided eye.

As a matter of law, it is fundamental that the absence from a reference of any one claimed element negates anticipation, *Kloster Speedsteel AB v. Crucible, Inc.,* 253 F.2d 1365, 230 USPQ 81 (Fed.Cir. 1986). Here, the claimed features delineated above are missing. The situation here is therefore not that of a claim to a new property of a known material. Further, the Courts have directed that the focus in assessing anticipation must always be on the entirety of the claimed invention, with the meaning of claimed elements determined in light of the specification and file history. *Structural Rubber Products Co. v. Park Rubber Co.*, 749 F.2d 207, 233 USPQ 377 (Fed.Cir. 1989); *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed.Cir. 1984). Here, as discussed above, the Reif '200 reference is directed to a different solution of a different problem; reading the pending claims in light of the specification cited above, it is clear that Reif '200 does not anticipate or suggest the claimed invention.

The present claims also define patentably over Reif '200 and the other art of record, whether taken alone or in any combination. The pending claims are clearly allowable. Acceptance of this application is earnestly solicited.

Should the Examiner have any questions or note any problems that could be addressed with an Examiner's Amendment, Applicant invites the Examiner to telephone the undersigned. (Please note that Edwards & Angell, LLP merged with Palmer & Dodge LLP effective November 1, 2005. The name of the merged firm, Edwards Angell Palmer & Dodge LLP, appears below. The address and telecommunications numbers remain the same.)

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Respectfully submitted,

By _____

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